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Eli Lilly and Company

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

NEKTAR THERAPEUTICS,

Plaintiff/Counter-Defendant,

v.

ELI LILLY & CO.,

Defendant/Counter-Claimant.

CASE NO. 3:23-CV-03943-JD

DEFENDANT ELI LILLY AND COMPANY'S NOTICE OF MOTION AND MOTION FOR COMPLETE OR PARTIAL SUMMARY JUDGMENT

Judge: Hon. James Donato
Hearing Date: July 17, 2025
Time: 10:00 a.m.
Courtroom: 11, 19th Floor

NOTICE OF MOTION & MOTION

TO ALL PARTIES AND THEIR COUNSEL OF RECORD:

PLEASE TAKE NOTICE THAT on July 17, 2025 at 10:00 a.m., or as soon thereafter as this matter may be heard, in the United States District Court for the Northern District of California, located at 450 Golden Gate Avenue, San Francisco, CA, 94102, in Courtroom 11, 19th Floor, before the Honorable James Donato, Defendant Eli Lilly and Company ("Lilly") will and hereby does move for complete or partial summary judgment pursuant to Federal Rule of Civil Procedure 56.

This Motion is based on this Notice of Motion, Motion for Complete or Partial Summary Judgment, the following Memorandum of Points and Authorities, the accompanying Declaration of Ryan Moorman, all other pleadings and papers on file in this action, any matters upon which the Court may take judicial notice, the arguments of counsel, and any other matters the Court may properly consider.

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ISSUE TO BE DECIDED

Whether Defendant Eli Lilly and Company is entitled to summary judgment because the undisputed material facts and plain terms of the parties' contract establish that Plaintiff Nektar Therapeutics cannot prove breach of contract or cognizable damages caused by an alleged breach.

INTRODUCTION

In 2017, Plaintiff Nektar Therapeutics asked Defendant Eli Lilly and Company to help develop an investigational compound called REZPEG into a medication for treating autoimmune conditions like lupus and atopic dermatitis ("AtD"). The parties entered into a License Agreement, under which Lilly made a $150 million upfront cash payment to Nektar and agreed to use Commercially Reasonable Efforts ("CRE") to help develop REZPEG and bring it to market, with Lilly's efforts to be measured solely against Lilly's efforts on its other comparable lupus and AtD products. Nektar would be eligible for additional payments only if REZPEG met certain developmental milestones, and Nektar would receive royalty payments ranging from [redacted] for a limited period following any commercial launch.

The development of pharmaceuticals is highly uncertain, and the parties foresaw that they might disagree about how to develop REZPEG and their respective interests in continuing to do so. Accordingly, Lilly bargained for several protections that preclude *post hoc* efforts to second-guess the myriad judgments the parties made over the six-year period that they jointly developed REZPEG. To begin, Lilly bargained for the right to end the partnership and return REZPEG without further risk. Although Lilly hoped at the start that REZPEG could help patients, the reality is that most potential medications fail, and the Agreement gave Lilly the unilateral power to "terminat[e] at will" if it no longer saw REZPEG's promise (or disagreed with Nektar about that promise). Ex. 1 §11.2. Should litigation somehow follow, Nektar expressly waived its ability to seek "lost profits." *Id.* §10.6.

To prevent after-the-fact efforts to blame Lilly for any failures, moreover, Lilly's duty to advance REZPEG was limited by an internal-facing Commercially Reasonable Efforts clause ("CRE"). Under that language, Lilly needed only to expend "effort, expertise and resources" as measured against "a comparable [Lilly] pharmaceutical product" "on an Indication-by-Indication" basis. *Id.* at 3-4. The CRE clause did not speak to Lilly's judgments or insure against errors, much less guarantee any result. Rather, if Nektar had concerns about Lilly's methods, it could raise them through a specific governance and "dispute

resolution" framework. *Id.* §3.7(b). But, at the end of day, the parties agreed that disputes "shall be resolved … consistent with [redacted]. *Id.* (emphasis added). Nektar did not have a right to further appeal or sue over such decisions.

Over the next six years, Lilly invested another [redacted] (over and above its initial $150 million payment), as well as the time and effort of numerous Lilly employees, on clinical trials and other efforts to develop REZPEG into a commercial product. Unfortunately, these efforts were not successful. A Phase 2 clinical trial for lupus failed to meet the parties' agreed-upon end points. It also became clear that REZPEG often caused significant injection-site reactions ("ISRs")—including baseball-sized irritations and inflammations that persisted for weeks—raising serious concerns about REZPEG's prospects for FDA approval and commercial viability. Following these developments, Nektar asked Lilly to exercise its unilateral right to terminate the Agreement. Lilly agreed to do so, surrendering its entire nine-figure investment. Nektar still believes in REZPEG (which is the main drug in its portfolio), and it is now free to develop REZPEG on its own or find a new development partner who shares its vision. If those efforts are successful, Nektar will enjoy REZPEG's full economic upside and Lilly will get nothing.

Not content with having obtained a [redacted] dollars of value from Lilly and the relinquishment of Lilly's contractual right to profit from any commercialization of REZPEG, Nektar now sues for more. It accuses Lilly of having breached the Agreement's CRE provision—and in particular of not exercising CRE to develop REZPEG for lupus and AtD indications—as well as of having violated the implied duty of good faith and fair dealing. It also asserts that Lilly breached a post-termination obligation to return materials and information to Nektar.

All of these claims fail as a matter of controlling New York law for two independent reasons: lack of recoverable damages, and lack of any breach. *Id.* §12.12 (choice-of-law clause). Indeed, Nektar's theories fundamentally upend the parties' bargain by repeatedly circumventing the plain text of the Agreement that limited Lilly's obligations, forbade Nektar from second-guessing Lilly's judgments, and curtailed potential damages.

No Cognizable Damages Caused By Alleged Breaches. Nektar asserts two theories of harm, but neither can survive summary judgment. First, Nektar claims it has been deprived of future milestone or royalty payments that it might have earned under the Agreement had REZPEG progressed further in

the development process. But the terms of the Agreement squarely foreclose this theory. It is undisputed that REZPEG never hit the contractually defined milestones that might have entitled Nektar to additional payments from Lilly. Lilly's intervening termination at will before REZPEG hit those milestones—a termination which Nektar expressly ***demanded***—cut off any obligation for Lilly to make future milestone or royalty payments under the Agreement. Lilly is entitled to summary judgment on this theory of liability.

Second, Nektar argues that Lilly delayed REZPEG's development, reducing REZPEG's hypothetical future commercial prospects. The Agreement squarely forecloses this theory of liability too. Except in circumstances not present here, the parties agreed that neither would be liable to the other "FOR REMOTE, SPECULATIVE, PUNITIVE OR EXEMPLARY, OR OTHER SPECIAL DAMAGES, ***INCLUDING LOST PROFITS***, ARISING OUT OF THIS AGREEMENT BASED ON CONTRACT, TORT OR ANY OTHER LEGAL THEORY." *Id.* §10.6 (emphasis added). Nektar may think that Lilly's alleged actions will result in REZPEG (hypothetically) producing a smaller return, but the parties expressly agreed to waive such claims.

No Breach of CRE Obligations. The notion that Lilly's years of effort and nine-figure investment somehow amounted to a failure to exercise "commercially reasonable efforts" to develop REZPEG is absurd. At bottom, Nektar complaints are not about Lilly's ***efforts***, but rather about supposedly "[redacted]" along the way. Ex. 2, Robin Tr. 138:8-20 (emphasis added). None of those criticisms implicate the commercial reasonableness of Lilly's efforts, much less show that Lilly's efforts fell short of the efforts that Lilly expended on a "comparable" medication for the same "[i]ndication," as required by the Agreement's inward-facing CRE provision. Ex. 1 at 3.

First, Nektar second-guesses Lilly's [redacted] for a lupus indication after a Phase 2 clinical trial failed to meet the measures by which the parties had agreed the trial would be judged. Ex. 3, Rao Rep. ¶75. That is a nonstarter under the text of the CRE provision. Nektar's frontal attack on Lilly's [redacted] *id.*, cannot show a shortfall in Lilly's normal "efforts, expertise and resources." Ex. 1 at 3. There is no contractual basis for Nektar to challenge the ultimate exercise of Lilly's judgment about REZPEG's performance in the trial—especially when Lilly had the contractual right to walk away under the termination provision.

Second, Nektar argues that Lilly mishandled the design of REZPEG's AtD trials by undertaking a

"rethink" of trial design after learning that efforts to mitigate REZPEG's ISRs had failed. Once again, this claim is a naked attack on Lilly's judgments about how best to position REZPEG in a complex market—not an attack on Lilly's level of efforts, expertise, and resources. Indeed, Nektar's arguments turn Lilly's CRE obligations on their head. In effect, Nektar complains that Lilly did ***too much*** by ***overanalyzing*** what patient population would be most appropriate, what data should be considered, and how to overcome ISRs and other challenges. Nektar might have been more willing to forego a rigorous evaluation of REZPEG, but it cannot substitute its judgment for Lilly's.

Third, Nektar complains that a subcontractor miscalculated one piece of data regarding REZPEG's Phase 1 effectiveness in treating AtD and that Lilly did not catch the mistake. But here, too, Nektar does not premise its claim on the efforts Lilly expended. Lilly was obliged only to expend commercially reasonable efforts, expertise, and resources, and Lilly nowhere promised that no errors would ever occur in numerous trials across a multiyear development process. Nektar has produced no evidence that the actual efforts Lilly used in engaging a subcontractor—which Nektar recommended—were out of line with those Lilly used in developing comparable products.

No Breach of Implied Covenant. In addition to its primary claim of breach of contract, Nektar tries to repackage its grievances under New York's implied covenant of good faith and fair dealing. That tactic fails because an implied-covenant claim cannot "concern[] the same underlying facts" as a plaintiff's contract claim. *InspiRx, Inc. v. Lupin Atlantis Holdings SA*, 554 F. Supp. 3d 542, 566-67 (S.D.N.Y. 2021). Nektar's attempt to second-guess Lilly's choices also violates the rule that "[t]he duty of good faith cannot add to, detract from, or alter the terms of the contract itself." *Warner Theatre Assocs. L.P. v. Metro. Life Ins. Co.*, 1997 WL 685334, at *6 (S.D.N.Y. Nov. 4, 1997), *aff'd* 149 F.3d 134 (2d Cir. 1998). Nektar's implied-covenant claim fails for the same reasons as its breach of contract claim, and certainly can get Nektar no more than what the parties actually bargained for.

No Post-Termination Breach. Nektar fares no better with its allegation that Lilly violated a post-termination duty to cooperate in returning REZPEG-related materials—namely the contents of the [redacted]. That claim must end at summary judgment because Nektar recently conceded that [redacted]. Ex. 4, Fanton Tr. 179:21-25, 182:9-17. Nektar cannot show a breach of the post-termination cooperation provision, let alone any injury caused by such a breach.

For all of these reasons, Lilly is entitled to summary judgment.

BACKGROUND

I. LILLY PAYS $150 MILLION FOR THE RIGHT TO EVALUATE REZPEG.

In 2017, Lilly and Nektar executed an Agreement granting Lilly the right to investigate, develop, and commercialize Nektar's "investigational compound" REZPEG. Ex. 1 at 1. Lilly hoped that REZPEG might "be useful in the treatment of autoimmune diseases." *Id.* But as Lilly and Nektar both knew, pharmaceutical development is an uncertain endeavor, such that "the risk of failure remains high" and there could "be no guarantee … that [REZPEG would] yield commercially successful products." *Id.* §12.7(a) & Sch. 12.7. Only if REZPEG's development resulted in sales or hit certain milestones—the first of which was the initiation of a Phase 3 trial—would Nektar receive further payments under the Agreement. *E.g.*, *id.* §§6.2, 6.3. Nektar does not contend that REZPEG hit any of those milestones.

After making an initial $150 million payment to Nektar, Lilly spent another [redacted] and several years conducting numerous clinical trials to explore REZPEG's potential for the agreed-upon indications of lupus and AtD. Ex. 5, Buthusiem Rep. ¶84. Lilly had strong incentive to make that investment because Lilly had the most to gain from REZPEG: up to [redacted] Ex. 1, §6.3. [redacted] Ex. 6, Mostaghimi Rep. ¶71 (emphasis added).

Because Lilly was assuming most of the risk and doing most of the work, the Agreement contained several terms protecting Lilly's interests and limiting Nektar's ability to interfere with Lilly's judgments. Nektar agreed that Lilly could conclude that REZPEG was not worth developing and walk away without further obligations. The Agreement expressly permitted "Termination At Will by Lilly," except in the limited circumstance where REZPEG had received full regulatory approval and made its first commercial sale (in which case termination would be briefly tolled). Ex. 1, §11.2. Termination at any other point—here, during clinical trials—required Lilly to pay nothing more. Nektar's recourse would be to keep the initial payment of $150 million and regain the full rights to REZPEG. *Id.* §11.4(b). A limitation-of-liability provision expressly barred "lost profits" claims. *Id.* §10.6.

Although the Agreement required Lilly to use CRE to develop REZPEG, the parties agreed to an

"inward facing" definition of CRE that restricted each parties' obligations to their "own standard[s]" for drug development. *Russell v. Zimmer*, 82 F.4th 564, 569-70 (7th Cir. 2023) (distinguishing "outward facing" CRE definitions that look to "industry standards"); Ex. 1 at 3-4. Here, there were two key components to the CRE definition.

First, the Agreement limited the parties' obligations to the expenditure of "effort, expertise and resources." Ex. 1 at 3. The CRE provision did ***not*** subject judgments or errors to inspection, much less require Lilly to use any particular process or achieve any outcome.[1]

On the contrary, the parties devised a separate process for addressing judgments and resolving disagreements. The Agreement established a Joint Steering Committee with general oversight of the development program, and, under it, a Joint Product Team responsible for implementing the product development plan. Ex. 1, §§3.1, 3.2, 3.4. Both groups included an "equal number" of Lilly and Nektar representatives, and development decisions had to be "unanim[ous]." *Id.* §3.1, 3.7(a); *accord* Ex. 7, Zalevsky Tr. 39:22-24 ([redacted]). In the event of any disagreements, the Agreement set out a formal "Dispute Resolution" process for escalating them. Ex. 1, §3.7.

Notably, that process—as relevant to the developmental activities here—would culminate with any intractable disagreements being "resolved consistent with … [redacted] *Id.* §3.7(b)(i). During the "[redacted] would have controlled. *Id.* But later in the development process, as occurred here, "[redacted]" would prevail. *Id.* The parties did ***not*** agree to allow further critiques of Lilly's choices through additional procedures like arbitration or litigation. *Id.*

Second, the parties agreed that CRE would be assessed using an inward facing provision that looks to the "effort, expertise and resources normally used by [Lilly] in the development and/or commercialization of a comparable pharmaceutical product Controlled by [Lilly] which is of similar

[1] Ex. 1 at 3-4 ("'Commercially Reasonable Efforts' or 'CRE' means effort, expertise and resources normally used by the Party in the development and/or commercialization of a comparable pharmaceutical product Controlled by such Party which is of similar market potential at a similar stage of development or commercialization in light of issues of safety and efficacy, product profile, the competitiveness of the marketplace, the proprietary position of the compound or product, the regulatory structure involved, the profitability of the applicable products, product reimbursement and other relevant strategic and commercial factors normally considered by the Party in making product portfolio decisions. For purposes of clarity, Commercially Reasonable Efforts will be determined on an Indication-by-Indication and country-by-country basis within the Territory, and it is anticipated that the level of effort may be different for different Indications and countries and may change over time, reflecting changes in the status of the Product and the Indications and country(ies) involved.").

market potential at a similar stage of development or commercialization in light of" numerous factors, including "relevant strategic and commercial factors normally considered by [Lilly] in making product portfolio decisions." *Id.* at 3-4. This benchmark of a comparable Lilly "product" was further limited to "an Indication-by-Indication" basis—here, lupus and AtD. *Id.* at 4.

II. LILLY SPENDS [redacted] DEVELOPING REZPEG.

Pharmaceutical development is a protracted, costly, and uncertain business. Most medications undergo at least three rounds of trials—Phases 1, 2, and 3—with each phase involving additional layers of review for safety, efficacy, dosing, and differentiation from existing products. *E.g.*, 21 C.F.R. §312.21 (describing phases). Trials are expensive and time consuming. A typical Phase 2 trial costs nearly $60 million and lasts three years (as of 2013); a Phase 3 trial can be even more extensive, enrolling thousands of participants. Ex. 5, ¶¶28, 32-33. All told, the average cost of conducting Phase 2 and Phase 3 trials and seeking regulatory approval exceeds $300 million. *Id.* ¶158. Here, Lilly pursued two indications—lupus and AtD—over ***seven*** trials. Ex. 6, ¶71.

Lupus. Lupus is a chronic autoimmune disorder in which the body's immune system attacks its own tissue. Ex. 6, ¶55. To evaluate REZPEG's potential for treating lupus, the parties collaboratively designed a Phase 2 study that sought to evaluate patient responses according to various scientifically accepted measures of disease activity. The parties agreed that the study's primary endpoint would measure the reduction of lupus activity on the Systemic Lupus Erythematosus Disease Activity Index (SLEDAI-4), and they agreed to use secondary endpoint measures based on the Systemic Lupus Erythematosus Responder Index (SRI-4) and the British Isles Lupus Assessment Group Assessment (BICLA or BILAG). *Id.* ¶76; Ex. 8, LLY00233685 at 691-692. The study's critical success factors were based on SRI-4 and BICLA. Ex. 9, LLY00208934 at 938 [redacted] *see also* Ex. 10, LLY00003877 at 880; Ex. 11, LLY00005412-COLOR at 418-COLOR; Ex. 12, LLY00004884 at 887; Ex. 13, LLY00221021 at 023, 024. Nektar admits that the parties were [redacted] Ex. 7, 102:10-103:1, 144:21-145:4.

Nektar also admits that REZPEG missed its primary endpoint, missed one critical success factor (SRI-4) for all three tested doses, and missed the other critical success factor (BICLA) on all but one dose. Ex. 14, 2/23/2023 Nektar Press Release; *see also* Ex.15, LLY00174619 at 622; Ex. 16, LLY00737556;

Ex. 17, LLY01068180 at 183. After evaluating the data, Lilly decided not to pursue further development of REZPEG for lupus and informed Nektar. Ex. 17, at 183-84; Ex. 18, LLY02459216 at 218; Ex. 16.

AtD. AtD is a form of eczema. Ex. 6, ¶23. Since 2017, the AtD market has been dominated by the medication Dupixent, which has [redacted] *Id.* ¶¶37-39. As Nektar admits, physicians had a [redacted] Ex. 19, Nektar00001316536 at slides 20-22. Other companies launched treatments while the parties were evaluating REZPEG; these FDA-approved medications gave physicians an increasingly broad array of options—including for patients who did not respond well to Dupixent. *Id*. at slide 22. Nektar recognized that [redacted] *Id*. at slide 23.

Lilly nonetheless evaluated REZPEG for AtD. Unfortunately, trials confirmed previous data that REZPEG caused frequent ISRs [redacted]. Ex. 20, LLY00825885; Ex. 21, LLY00893898 at 910-11; Ex. 22, LLY00004865 at 874; Ex 23, LLY00235661 at 668. [redacted] Ex. 24, Nektar00000957710 at 769 (emphasis added).

These ISRs were not trivial. Patients experienced "[redacted]" sized reactions that were prominent and lasted for weeks, often until the patient's [redacted] Ex. 25, Ashrafzadeh Tr. 86:14-87:6; Ex. 26, Kotzin Tr. 97:11-99:24; Ex. 27, LLY00006185-COLOR at 216-COLOR; Ex. 28, LLY02262535 at 537. Nektar's expert concedes that [redacted] Ex. 29, Mostaghimi Tr. 182:17-183:9. [redacted] Ex. 30, LLY00977763.[2] Nektar internally recognized that ISRs constituted [redacted] Ex. 32, Nektar00000138589 at 2. And its own expert in this case concedes that the ISRs [redacted] Ex. 29, 87:6-89:1, 159:22-160:1.

Lilly spent considerable time and money evaluating several potential solutions, but despite its

[2] Post-termination, [redacted] Ex. 31, Nektar00000936124, slide 12.

efforts the ISR problem was insurmountable. *Id.* at 205:2-9. Lilly conducted a clinical study examining whether topical steroids mitigated ISRs. Ex. 33, LLY02468615 at 617. They [redacted] Ex. 34, LLY00123657 at 658; Ex. 35, LLY00123660 at 689. Lilly's study of oral antihistamines to mitigate ISRs was also [redacted] Ex. 36, LLY00006180 at 182; Ex. 37, LLY00006249 at 253, 270-271. Indeed, "all patients" showed ISRs. *Id.* And other efforts to explore variations in the [redacted] failed. Ex. 38, LLY01333740 at 742. As Nektar later conceded, the insurmountable nature of the ISR problem [redacted] thus frustrating a solution. Ex. 26, Kotzin Tr. 134:3-23, 80:20-81:2; Ex. 29, 204:24-205:1.

III. AT NEKTAR'S REQUEST, LILLY TERMINATES THE AGREEMENT AND RETURNS REZPEG.

All told, [redacted] across several years [redacted]" Ex. 6, ¶71. Despite Lilly's vast efforts and expenditures, however, Nektar supposedly became [redacted] Ex. 2, 138:8-20. If Nektar had truly believed that Lilly had breached its CRE obligations, it could have invoked §11.3 of the Agreement, which gave Nektar the right to terminate for cause. But it did not. Instead, Nektar asked Lilly to voluntarily terminate the Agreement and [redacted] Ex. 2, 140:20-24, 143:21-144:1.

At Nektar's urging, Lilly did so on April 23, 2023, and began transferring materials to Nektar. Ex. 39, LLY02042216, at 218-19; Ex. 40, LLY00736684; Ex. 41, LLY01347305; Ex. 42, LLY01189685. That let Nektar keep the $150 million upfront payment, retain the value of the additional [redacted] Lilly had invested, and regain full rights to REZPEG and any future profits. Ex. 6, ¶86; *accord* Ex. 2, 67:24-68:5, 79:6-10, 152:6-10, 168:22-25; Ex. 43, Ruddock Tr. 281:16-20, 283:2-6, 299:4-9 (conceding that Nektar would [redacted]). If, as Nektar contends in this lawsuit, REZPEG is a commercially viable product, then the termination was a gift to Nektar.

IV. NEKTAR SUES.

After asking Lilly to walk away from its [redacted] dollar investment, Nektar filed this lawsuit,

premised on the bizarre theory that REZPEG actually was a promising medication, yet that Lilly walked away from a potential blockbuster for which Lilly would have reaped the vast majority of profits. In support of that view, Nektar asserts speculative damages theories based on three contract-related counts.

CRE Claim. Nektar's primary contract theory is that Lilly breached the CRE provision by not using "commercially reasonable efforts in designing and conducting the[] studies, in developing REZPEG, and in bringing it to market." ECF 61 at ¶86. Nektar alleges three variants of this supposed breach:

First, Nektar claims that Lilly breached when it [redacted] after REZPEG failed its Phase 2 endpoints. Ex. 3, ¶75. As a corollary to this attack on Lilly's judgment about whether further development was warranted, Nektar asserts that Lilly mismanaged the "[redacted] *Id.* ¶75.

Second, Nektar alleges that Lilly, after receiving ISR data showing that REZPEG was unlikely to supplant Dupixent as the go-to choice for a first-line AtD treatment, was wrong to "[redacted]" the design of the Phase 2 AtD trials. Ex. 3, ¶74. In particular, Nektar disputes [redacted] *Id.* In Nektar's view, the trial should have concentrated on "[redacted]. *Id.* Nektar also claims that Lilly incorrectly proposed [redacted] for the Phase 2 AtD study. *Id.*

Third, Nektar asserts that a subcontractor miscalculated one piece of data regarding REZPEG's Phase 1 effectiveness in treating AtD, [redacted] Ex. 6, ¶14(i); Ex. 3, ¶74. Although Nektar does not dispute that Lilly had the right to subcontract such calculations, *see* Ex. 1 §4.10, or that Lilly [redacted] Ex. 2, 191:17-25, Nektar nonetheless contends that Lilly breached its contractual duties by not catching a math error.

Good Faith Claim. As a backstop to its CRE claims, Nektar derivatively claims that Lilly breached the "implied covenant of good faith and fair dealing" by delaying the development of REZPEG, "as detailed above." ECF 61 at 30. In other words, Lilly's supposed breach of the Agreement also breached Lilly's implied duty to act in good faith. Beyond that facially duplicative theory, Nektar suggests that the termination of the Agreement (at Nektar's demand) somehow violated Lilly's duty of good faith.

Post-Termination Breach Claim. Nektar asserts a breach of Lilly's post-termination duty to

return [redacted] *See* Ex. 44, Nektar's Rog. Resp. No. 17 at 13-14. Yet Nektar has identified nothing that is actually missing from the file, [redacted]. Ex. 4, 182:9-17.

Damages. Nektar asserts two categories of damages.

First, Nektar asserts that it is entitled to milestone and royalty payments, even though the Agreement required Lilly to make these future payments only upon certain events such as REZPEG proceeding to late-stage trials, receiving regulatory approval, and ultimately reaching patients through commercial sales. Ex. 1 §§6.2, 6.3. Nektar does not contend that REZPEG ever hit those vital milestones.

Second, Nektar argues that Lilly has somehow reduced the value of REZPEG, such that Nektar has diminished earnings expectations. But the Agreement expressly bars the recovery of lost profits.

LEGAL STANDARD

Summary judgment is proper when "there is no genuine issue as to any material fact." *Oliver v. Microsoft*, 966 F. Supp. 2d 889, 894-95 (N.D. Cal. 2013). Nektar cannot "simply … alleg[e] some factual dispute between the parties," but must identify "material facts, i.e., facts that might affect the outcome of the suit." *Id.* at 895; *accord InspiRx*, 554 F. Supp. 3d at 552 (granting summary judgment on CRE claim).

ARGUMENT

Summary judgment is proper on two independent grounds: lack of damages, and lack of breach.

I. NEKTAR'S CLAIMS FAIL FOR LACK OF DAMAGES.

Lilly is entitled to summary judgment because the alleged breaches did not cause cognizable injury or damages recoverable under the terms of the Agreement. "[A] clear demonstration of damages" is required to survive "summary judgment," *Milan Music*, 829 N.Y.S.2d at 486, because "[t]he essential elements of a cause of action" include "damages resulting from the breach," *R. Vig Props*, *v. Rahimzada*, 184 N.Y.S.3d 782, 786 (N.Y. App. Div. 2023); *e.g.*, *Mejias v. Amazon Corp. Headquarters*, 225 N.Y.S.3d 533 (N.Y. App. Div. 2024) (summary judgment when the "alleged breach of contract … did not cause plaintiffs' alleged injuries"); *Milan Music*, 829 N.Y.S.2d at 486 (summary judgment for lack of a "clear demonstration of damages"). The Court does not need to resolve factual questions to grant summary judgment on this issue. Rather, every form of asserted damages is unavailable as a matter of law.

A. Nektar Cannot Recover Additional Milestone Or Royalty Payments.

Nektar's first theory is that it lost out on payments under the Agreement's "[redacted]" provisions, which would have been triggered if—and only if—REZPEG had advanced to later stages of development or commercial sales. Ex. 3, ¶40; Ex. 44, Resp. No. 17 at 11-12 (claiming that if "[redacted]"). But Nektar did not receive those payments because REZPEG never advanced to those stages, and Nektar does not contend otherwise.

The plain text of the Agreement precludes Nektar from asserting that Lilly should have moved forward with REZPEG so that Nektar could collect additional payments. When Lilly paid $150 million and signed the Agreement, it bargained for the right to walk away at any time prior to commercial launch without incurring any additional obligations. The Agreement permitted "Termination ***At Will***," which allowed Lilly to "terminate this Agreement ***in its entirety***." Ex.1 §11.2 (emphases added). That right is incompatible with Nektar's theory that Lilly had an obligation to [redacted] so that Nektar might claim more [redacted] Ex. 44, Resp. No. 17 at 11-12.

New York law confirms that Nektar cannot negate the termination provision by requiring Lilly to make payments that would have been available only absent the intervening cause of a termination. When a plaintiff's supposed "right to" a contractual payment can "be defeated at will" by the defendant's "notice of termination," "there is no basis for recovery of any part of the prospective [payment]." *Gilsey v. Wm. Hengerer*, 147 N.Y.S.2d 210, 210-211 (N.Y. App. Div. 1955). The reason for this rule is obvious. Requiring payment under such circumstances would effectively nullify an at-will termination provision, thus violating the settled New York rule that courts will not "rewrite the contractual terms that the parties have freely negotiated." *Local 832 v. Dep't of Educ.*, 876 N.Y.S.2d 30, 32 (N.Y. App. Div. 2009).

Nektar's demand for additional milestones is especially inappropriate because the Agreement ***elsewhere*** creates a narrow limitation on termination to protect future payments to Nektar under ***other*** circumstances. The termination clause provides that Lilly's at-will termination right "shall be tolled for a period of [redacted] from the date of the [redacted]"—i.e., ***after*** commercial launch, Lilly would be required to continue the Agreement for a year. Ex.1 §11.2 That specific protection for certain future payments stands in sharp contrast to the situation here, where Lilly

terminated well before [redacted]. Thus, under the rule that "expression of one thing is the exclusion of another," the parties' decision to "express[]" one limitation on Lilly's ability to cut off payments via termination (which is not applicable here) necessarily "exclu[des]" any implicit limitation on Lilly's ability to cut off payments via termination before REZPEG reached commercial sales. *Deth v. Castimore*, 281 N.Y.S. 114, 120 (N.Y. App. Div. 1935). Nektar is entitled to no further milestone, royalty, or other payments under the Agreement, and instead must content itself with the $150 million upfront payment it already received from Lilly, the value of Lilly's additional [redacted] investment in REZPEG's development, and Lilly's relinquishment of any right to REZPEG's future profits.

B. Nektar Cannot Recover For Alleged Harm To REZPEG's Value.

Nektar's second theory of harm is even more attenuated. It alleges that Lilly ***decreased*** REZPEG's future profitability by delaying development and raising concerns about REZPEG's viability. In Nektar's view, [redacted] Ex. 3, ¶11. Its purported method of assessing this harm is to [redacted] *Id.*

Even if this theory were not hopelessly "speculative" (a fatal problem in itself, *e.g.*, *InspiRx*, 554 F. Supp. 3d at 563-65), the Agreement's limitation-of-liability provision squarely precludes it. The parties stipulated that, except in circumstances not present here, neither of them would "be liable for remote, speculative, punitive or exemplary, or other special damages, ***including lost profits***, arising out of this Agreement based on ***contract***, tort ***or any other legal theory***." Ex. 1 §10.6 (emphases added).

That language is fatal to Nektar's theory of recovery, which rests on the premise that Nektar would have reaped additional profits from REZPEG absent the alleged breach. To quote Nektar's expert, Nektar's approach seeks to [redacted]

[redacted]. Ex. 3, ¶76. No matter the labels and terminologies Nektar would affix to this theory, that purported delta between the two hypothetical scenarios is "a lost profits analysis"—i.e., "the economic loss suffered by a business." *Capstone v. Navarrete*, 2018 WL 6786237, at *5 (S.D.N.Y. Dec. 13, 2018); *see also That's What She Said v. Gutter Games*, 2024 WL 3678473, at *16-18 (S.D.N.Y. Aug. 5, 2024) (granting summary judgment on the basis of a limitation-of-liability provision when "Plaintiff s[ought] to recover the profits that it lost due to Defendants' breach of the License Agreement").

The terms of the Agreement could not be clearer that such a claim is not viable, requiring summary judgment. As the parties recognized at the outset, pharmaceutical development is a "risk[y]" endeavor characterized by frequent "failure[s]," unforeseen problems, and "dispute[s]" about how to proceed. Ex. 1 §3.7 & Sch.12.7. In light of these realities, Lilly bargained for strong protections, such as an at-will right to walk away and a limitation-of-liability provision that barred a broad range of damages, including "lost profits." *Id.* §10.6. Having already ***massively*** profited from Lilly's investment in REZPEG—a nine-figure expenditure Lilly will never recover—Nektar cannot now come back to the trough and seek even more money from Lilly.

C. Nektar Has No Theory Of Harm Based On The REZPEG Materials.

Discovery confirmed that Nektar has no viable damages theory with respect to its (unfounded) claim that Lilly delayed in returning [redacted]. Nektar has not explained how the supposed delay impaired the value of REZPEG. Indeed, its expert did not even attempt to offer an opinion on the issue. That itself requires summary judgment, "because without [such] expert testimony" Nektar cannot demonstrate with the requisite degree of confidence how the supposed lack of [redacted] impacted the complex scientific process of developing, approving, and commercializing a medication. *Barnhart v. Home Depot U.S.A.*, 2007 WL 7700435, at *3 (N.D.N.Y. Mar. 30, 2007) (granting summary judgment after excluding expert testimony).

In addition, Nektar has often admitted to the lack of harm. Its own documents concede that [redacted] Ex. 45, Nektar00000141822. Nektar could not say how any purportedly missing documents would be [redacted] Ex. 4, 181:6-182:8. And it could not even explain how it [redacted]

[redacted] *Id.* These defects preclude Nektar from making the requisite "clear demonstration of damages" (let alone showing that Lilly caused such harm). *Milan*, 829 N.Y.S.2d at 486.

* * *

The plain text of the Agreement forecloses each of Nektar's damages theories. For this reason alone, Lilly is entitled to summary judgment.

II. NEKTAR'S BREACH THEORIES FAIL.

In addition, each of Nektar's breach theories—whether contractual or implied—is deficient. The Court should reject them all and end this case entirely.

A. Nektar's CRE Claims Fail.

Nektar's primary argument is that Lilly breached its obligation to use commercially reasonable efforts to develop REZPEG, but this notion is beyond farfetched where Lilly spent several years, [redacted], and countless hours of employee time working to make REZPEG a success. Lilly's efforts more than satisfied the "inward facing definition of commercially reasonable efforts" used in the Agreement, which required only that Lilly use efforts comparable to those it used for developing other, comparable Lilly products. *Russell*, 82 F.4th at 569. Such clauses "are inherently more friendly to the buyer" (Lilly) because they prohibit the seller (Nektar) from second-guessing Lilly's efforts by comparing them "to industry standards or to those of other similarly situated businesses." *Id.* at 570.

This particular CRE clause forecloses Nektar's Monday-morning quarterbacking in two respects.

First, it requires Lilly only to use "***effort, expertise and resources*** normally used by [Lilly]." Ex. 1 at 3 (emphasis added). It does ***not*** speak to Lilly's judgments, interpretations, or errors, nor does it require Lilly to use any particular process or approach. In other words, because "the contract speaks not of results but of efforts," Nektar cannot premise a claim on Lilly's alleged "failure to adopt strategies [that Nektar] viewed as desirable where the contract did not require [Lilly] to do so." *Bancroft Com. v. Goroff*, 2014 WL 7409489, at *7 (D. Md. Dec. 31, 2014) (rejecting CRE claim); *see also InspiRx*, 554 F. Supp. 3d at 557 (rejecting CRE claim that the defendant "disband[ed] its sales force" when "the Agreement did not require [defendant] to keep its [] sales force"); *see generally In re Trusts*, 375 F. Supp. 3d 441, 449 (S.D.N.Y. 2019) ("[C]ourts should be extremely reluctant to interpret an agreement as impliedly stating something which the parties have neglected to specifically include."). Nor can Nektar assert claims based

on alleged mistakes or errors in judgment by "couch[ing them] in the language of efforts." *Bancroft*, 2014 WL 7409489, at *7. The only way Nektar can survive summary judgment is through material evidence of deficiencies in Lilly's "efforts, expertise and resources." Ex. 1 at 3-4.

Second, and independently, Nektar must specifically measure Lilly's alleged miscues against "a comparable pharmaceutical product Controlled by [Lilly]" that was being developed for the same "indication"—*i.e.*, lupus or AtD. *Id.* Nektar cannot make generalizations about good research practices or assert an open-ended reasonableness standard. It must explain how the efforts, expertise, and resources that Lilly expended on REZPEG fell short when compared to the efforts, expertise, and resources that Lilly expended on a comparable lupus or AtD product.

Here, each of Nektar's efforts to nitpick REZPEG's development over six years and seven trials violates at least one (and usually both) of these limitations. The Court should reject them all.

1. Lilly was not required to advance REZPEG to a Phase 3 lupus trial.

Nektar says that Lilly breached the CRE provision when it [redacted] after REZPEG flunked its Phase 2 trial by missing the primary endpoint and failing to meet the agreed-upon critical success factors. Ex. 3, ¶75. But the CRE language does not allow Nektar now, long after the fact, to critique Lilly's clinical and commercial decisions.

A decision whether to advance a medication is a quintessential ***judgment*** and therefore falls outside the express terms of the CRE provision: "efforts, expertise and resources." Ex. 1 at 3-4. Nektar has all but admitted that this claim is a naked attack on Lilly's judgment. Its corporate representative agreed that it was ***not*** [redacted] Ex. 7, 180:24-181:5—thus confirming that this claim is nothing more than a battle of competing views. Similarly, Nektar's expert is [redacted] Ex. 29, 313:9-18 (emphasis added). Indeed, [redacted] *Id.*

Moreover, Nektar actually ***agreed*** with Lilly on the endpoint and success-factor metrics for REZPEG's trial performance. Ex. 10, at 880. Following that initial consensus, [redacted] Ex. 7,

144:21-145:4; Ex. 11; Ex. 9, at 937, 938; Ex. 13, at 023, 024. [redacted]. Ex. 7, 143:8-17, 144:17-20; Ex. 46, Nektar00000862440 at 441-42. That Nektar is now unhappy with endpoints and critical success factors—to which it previously agreed—says nothing of Lilly's efforts.

Equally flawed is Nektar's argument that Lilly erred in conducting [redacted] the study—i.e., by not enrolling extra participants beyond what was needed for statistically significant data. Ex. 3, ¶75. This theory fails for three reasons: (1) The enrollment level did not change the ultimate, undisputed, and material ***fact*** that REZPEG missed its Phase 2 endpoints. (2) Nektar [redacted] Ex. 47, LLY02472169, as shown by its [redacted] Ex. 48, Nektar00000720137 at 138. (3) Whether to overenroll a study is a quintessential judgment call that falls beyond the scope of the CRE provision. In the words of Nektar's witness, [redacted] Ex. 26, 166:19-24. Or, to quote its representative, [redacted] Ex. 43, 71:3-13. Because this routine trial-design call was a judgment—and, at that, a judgment to which Nektar agreed—Nektar cannot now attack it via a purported CRE claim.

If there were any doubt that Nektar is improperly using the CRE provision to attack a judgment call, the New York rule that "[a]ll parts of a contract must be read in harmony to determine its meaning" erases it. *Bombay Realty v. Magna Carta*, 790 N.E.2d 1163, 1165 (N.Y. 2003). The Agreement ***elsewhere*** speaks to the consequences of Lilly's judgments (and Lilly's power to make them), twice confirming that the CRE provision is an inappropriate tool for Nektar's second-guessing.

First, because the Agreement allowed "Termination At Will By Lilly," Ex. 1 §11.2, Lilly had no duty to push forward with a Phase 3 trial after REZPEG failed to meet its Phase 2 endpoints. Lilly did not pay nine figures to bind itself forever to chasing (and paying for) REZPEG.

Second, the Agreement contains an express "Dispute Resolution" framework, which Nektar could have used to voice disagreements about Lilly's design and evaluation of the study. Ex.1 §3.7(b). Nektar cannot now ask a jury to belatedly resolve Nektar's *post hoc* disagreements through the vehicle of a

lawsuit. That is especially true because the Agreement also makes clear that, in the event of such a disagreement, "[redacted]" would control, without giving Nektar any right to challenge (much less litigate) Lilly's decision any further. *Id.* Nektar's current view that REZPEG was entitled to a Phase 3 trial and that Lilly erred in deciding otherwise flouts the careful structure of the Agreement.

Finally, Nektar has not identified a Lilly ***comparator*** lupus medication which supposedly received better treatment than REZPEG. *E.g.*, *Russell*, 82 F.4th at 571 (rejecting CRE claim when plaintiff failed to "compare[] the earnout products to a comparable obligation with respect to another product or technology that is similar to the Earnout Products in terms of commercial potential, development stage, and product life"). The Agreement measures Lilly's efforts against those used by Lilly "in the development and/or commercialization of a comparable pharmaceutical product Controlled by [Lilly] which is of similar market potential at a similar stage of development or commercialization" "on an Indication-by-Indication basis." Ex. 1 at 3-4. Thus, even if Nektar's grievances about Lilly's judgments amounted to a showing of insufficient "effort, expertise and resources"—they do not—they would still fail for lack of a comparator medication on which Lilly expended greater efforts. *Id.*

2. Lilly exerted reasonable efforts in designing the Phase 2 AtD trial.

Nektar also attacks Lilly's judgments surrounding the Phase 2 AtD trial. In Nektar's view, Lilly wrongly engaged in a 2022 "[redacted]" of the trial [redacted] Ex. 3, ¶74; Ex. 44, Resp. No. 24. This is another impermissible assault on Lilly's judgments. If Nektar had any concerns about Lilly's assessments or "thinking," its sole avenue for raising them was the Agreement's dispute resolution mechanism, which ultimately would have empowered Lilly to make the final call. A basic review of the events confirms that Nektar's "rethink" theory is just a second-guessing of Lilly's judgments about how to best evaluate and position REZPEG to meet patient needs in a difficult market.

Study Population. Nektar first complaint—that Lilly redesigned the AtD trial to focus on bio-experienced patients—seeks to undermine Lilly's judgments. In Nektar's current view, the focus on bio-experienced patients meant that the study [redacted]. Ex. 44, Resp. No. 24.

But picking a target patient population is a judgment. Lilly's view was that bio-experienced

patients were important because REZPEG's ISR problems meant that it was a dubious candidate for use as a first-line treatment for skin conditions like AtD: if patients are [redacted] Ex. 50, 164. That problem was compounded by the fact that these patients ***already*** had available the first-line treatment option of Dupixent, which Nektar concedes had [redacted] Ex. 6, ¶¶37-39. Given these realities, Lilly believed REZPEG was most promising as a second-line treatment for patients who had tried Dupixent but were unsatisfied and looking for a second option—i.e., [redacted] patients for whom [redacted] Ex. 53, LLY00185780 at 7, 27; Ex. 49, at 092.

Nektar has acknowledged that choosing a study population is a judgment call. Nektar recognized that [redacted] Ex. 54, Nektar00000099647 at 1 (emphasis added). Nektar recognized that it [redacted] Ex. 26, 250:2-8, 256:7-15. And Nektar's own research confirmed that [redacted] Ex. 55, Nektar00000100411, at 413. In hindsight, for purposes of this suit, Nektar suggests that the shift to a bio-experienced population was a [redacted] Ex. 2, 138:13-20 (emphasis added). But the CRE clause does not speak to judgments at all—bad, or otherwise.

Moreover, any suggestion that Lilly's desire to focus on bio-experienced patients violated its CRE duty is nonsense because the redesign required Lilly to expend ***more*** "efforts" and "resources" in rethinking REZPEG and coming up with potential solutions to ISR problems. As the undisputed record shows, Lilly needed to spend extra time [redacted] Ex. 49, and conducting [redacted] into the question. Ex. 56, LLY00125612. Instead of summarily going through the motions of the initial trial design, Lilly went above-and-beyond in an effort to overcome challenges. That is the opposite of a lack of effort.

Even if Lilly's judgments could be reconstrued as a lack of effort, there is no genuine claim that Lilly's strategy for REZPEG fell short of Lilly's strategy for a "comparable pharmaceutical product" for an AtD "indication." Ex. 1 3-4. In reality, it was Lilly's [redacted]

[redacted]. Ex. 7, 212:8-18; Ex. 57, D. Murray Tr. 41:13-19, 90:7-9; Ex. 58, LLY02089480 at 485. Thus, after REZPEG's rampant ISRs proved unmitigable, [redacted] Ex. 59, Jonsson Tr. 158:14-159:25. Nektar ***agrees*** that this was Lilly's typical approach: [redacted] meaning that Nektar's real criticism here is that Lilly's high standards were too [redacted] Ex. 7, 136:18-138:2, 212:8-18. But the CRE clause does not permit such criticisms.

Interim Analyses. Nektar also contends that Lilly should not have designed the AtD trial to include [redacted] because the design met [redacted] Ex. 44, Resp. No. 24. This theory also fails to trigger the CRE provision.

To start, the parties agreed on the number and timing of the interim analyses that Nektar now attacks. When Nektar raised its objections to Lilly's initial interim-analysis plan, Lilly agreed, [redacted] and decide upon a new plan acceptable to both parties. Ex. 60, LLY00778732; Ex. 7, 273:9-19. After extensive discussions, the parties [redacted] Ex. 7, 273:9-19; Ex. 36, at 182; Ex. 61, LLY00945353. Nothing about that sequence is consistent with a claim that Lilly dropped the ball and failed to devote effort, expertise, and resources.

In addition, Nektar fails to identify a comparator medication that Lilly treated differently. To the contrary, Lilly proposed [redacted] *Compare* Ex. 36 (REZPEG), *with* Ex. 62, LLY02468632 at 9 (CD200R); *see also* Ex. 29, 253:21-254:24, 258:22-259:5 ([redacted]). That similar treatment is fatal under the CRE comparator clause.

* * *

Nektar dresses up its attacks on Lilly's development judgments with allegations that the "rethink" was nefariously motivated. But the CRE provision just measures efforts, expertise, and resources. And

Lilly approved the original AtD study design in January 2022, when it believed that cortisone steroids might mitigate ISRs. Ex. 38, at 742, 745, 750, 753; Ex. 33, at 617. But in approving funding, Lilly's governing board specifically recommended further [redacted] Ex. 33. Then, in February, data from the ISR study showed that the mitigation strategy [redacted] Ex. 34, at 658; Ex. 35, at 689. Thus, consistent with its initial admonition that ISR problems would require further evaluation, upon receiving the negative results the board proposed to await the gathering of further information about ISR data. Ex. 49, LLY01361090. Nothing about this sequence suggests Lilly exerted inadequate effort in development REZPEG. Indeed, in "rethinking" the study, Lilly exerted more effort than it would have by merely letting things play out.

Beyond this core problem that Nektar is just attacking judgments, the "rethink" theory also fails under the inward-facing ***comparator*** clause. Nektar ascribes ill-intent because Lilly approved funding for the initial trial design before changing the design. But the undisputed evidence shows that Lilly's [redacted] Ex. 50, Skovronsky Tr. 235:5-15, 62:9-19. In addition, Lilly's typical development strategy is [redacted] Ex. 50, 305:12-21. Indeed, [redacted] Ex. 51, Klekotka Tr. 322-323:17; Ex. 52, LLY02074922, at 926-28. Nothing in the CRE provision prevents Lilly from actively evaluating, incorporating, and responding to new data in designing multi-million dollar trials; rather, that is Lilly's usual practice.

In sum, Nektar's "rethink" theory is nothing more than a claim that Lilly should have devoted ***less*** time, attention, and resources to scrutinizing and positioning REZPEG than Lilly, in its judgment, deemed appropriate. That cannot create a genuine issue of fact that Lilly's expenditure of a [redacted] dollars was somehow a failure to make reasonable efforts.

3. Lilly did not breach the CRE provision by missing a math error.

Nektar's final CRE theory is that a subcontractor miscalculated data regarding REZPEG's

efficacy for treating eczema and that Lilly failed to catch the error when reviewing the data. Ex. 3, ¶74. This theory is divorced from the plain text of the CRE clause. Nothing in the CRE provision guarantees that Lilly (or its subcontractors) will never make mistakes or will catch all mistakes. It just requires Lilly to use reasonable "efforts, expertise or judgments," and Lilly never failed to do that. Ex. 1 at 3.

The uncontested evidence is that the relevant personnel were experienced and qualified statisticians who respectively had worked on "15 to 20" medications "for autoimmune diseases"—including AtD and lupus, *see* Ex. 63, Manner Tr. 52:7-17—and had 23 years of clinical experience over 45 trials, Ex. 64, Zou Tr. 96:7-10, 272:18-276:25, 278:24-279:8. Nektar's own statistician agreed that Lilly's REZPEG team included [redacted] Ex. 65, Yu Tr. 12:7-10. These same statisticians worked on multiple other early-phase Lilly assets, including CD200R, and Lilly continued to entrust them with overseeing the statistical analysis of its clinical trials following the alleged mistake. Ex. 63, 68:23-69:7, 22:6-9; Ex. 64, 17:20-18:1, 51:22-52:3, 8:24-25.

Moreover, the subcontractor who committed the underlying mistake is one that [redacted] Ex. 4, 77:7-15; Ex. 66, Jue Tr. at 83:14-20. Indeed, Nektar thought that the subcontractor was [redacted] Ex. 4, 79:15-18, 106:21-107:2.

Because Lilly's ***efforts*** were sufficient, all Nektar can offer is the *post hoc ergo propter hoc* speculation that, because a mistake was made, surely there must have been insufficient efforts somewhere up the line. That is an end run of the rule that a "cause of action alleg[ing] negligent performance of the contract … simply does not exist." *Megaris Furs v. Gimbel*, 568 N.Y.S.2d 581, 583 (N.Y. App. Div. 1991). The Agreement polices efforts, not outcomes, so the question is whether Lilly made reasonable efforts, and ***not*** whether some other approach might have "been undertaken to produce a better result." *Shane Campbell v. Frieze Events*, 838 F. App'x 608, 610 (2d Cir. 2020) (rejecting CRE claim). Nektar did not bargain for a standard of statistical or clinical care, nor for a promise that Lilly would never err.

Independently, Nektar's math-error claim also fails for the now-familiar reason that Nektar has no comparator medication. Nektar cannot show that the efforts Lilly made leading up to the mistake fell short when compared to Lilly's usual process. To the contrary—and once again—the uncontested record is that Lilly has used the at-issue personnel on numerous other projects. *Supra* 22.

Finally, Nektar's fallback theory that the error violated a schedule to the Agreement that included the "Eli Lilly and Company Good Research Practices" is meritless for two reasons. Ex. 1 Sch. 4.8.

First, §4.8 of the Agreement imposed solely on "***Nektar***" the obligation to follow those practices. That party-specific obligation makes sense. Lilly was the more-established pharmaceutical company and bore the vast majority of the costs and risks under the Agreement, so it wanted to ensure that Nektar would follow the standards Lilly set for development partners in discharging Nektar's limited tasks under the Agreement—for example, when Nektar carried out aspects of the "Initial Development Activities." Ex. 1 §4.4(a). Given that limited and unilateral obligation, ***Lilly's*** alleged noncompliance is not a breach.

Second, even if Lilly had contractually committed itself to following the schedule, there still would be no breach of the schedule's language. Nothing in the schedule promises mistake-free work. Rather, it states that "personnel" should be "qualified and can perform Study tasks to meet expectations." *Id.* Sch. 4.8. Lilly never breached those obligations. To the contrary—and as discussed above—Lilly assigned qualified personnel and contractors who worked on other Lilly and Nektar projects. *Supra* 22. That is dispositive under the plain text, which refers to qualifications and not to results. Similarly flawed is Nektar's observation that the schedule states that "[a]ll data included in reports must be reviewed to ensure that the reports accurately reflect the data." Ex. 1 Sch. 4.8. Nektar admits that Lilly did just that—[redacted]—but unfortunately happened to [redacted] Ex. 2, 191:21-25. But the schedule does not state a categorical assurance to catch any error that may exist; it just requires performing the review with the goal of accuracy. Lilly discharged that duty, and Nektar cannot conjure a nonexistent breach.

* * *

The facts do not support any of Nektar's CRE theories, and the Court should grant summary judgment on each and every one of them. The Agreement requires efforts, expertise, and resources, all of which Lilly supplied in abundance by making significant investments of time and resources. Nektar may want to second-guess [redacted] Ex. 2, 138:8-20, but the Agreement does not speak of [redacted]. And, Nektar cannot point to any comparator Lilly medication that Lilly treated more favorably. For any of these reasons, Lilly is entitled to summary judgment.

B. Nektar Cannot Pursue Its Backstop Implied-Covenant Claim.

Nektar's fallback claim under the "implied covenant of good faith and fair dealing" fails to establish a trial-worthy issue for three reasons. ECF 61 at 30.

First, this claim "concern[s] the same underlying facts" as the primary CRE contract claim. *InspiRx*, 554 F. Supp. 3d at 566-67 (granting summary judgment against good-faith claim alleged alongside CRE claim). Nektar's discovery responses confirm the duplicative nature of this claim, accusing Lilly of "fail[ing] to exercise CRE ***and/or*** good faith." *E.g.* Ex. 44, Resp. No. 18 at 15 (emphasis added); *id.* No. 17 at 11-13. This lumping approach is because Nektar's bad-faith claim rests on the same "factual predicate" that Lilly supposedly acted improperly in developing (or failing to develop) REZPEG. *InspiRx*, 554 F. Supp. 3d at 567. But under settled New York law, an implied-covenant claim that shares the "factual predicate" of an ordinary breach claim—like Nektar's CRE claim here—cannot proceed. *Id.*

Second, even if Nektar's good-faith claim were separable from its CRE claim, it would violate the rule that "the duty of good faith cannot add to, detract from, or alter the terms of the contract itself." *Warner*, 1997 WL 685334, at *6. Nektar's good-faith theories echo the refrain that Lilly made bad judgments and errors about whether and how to advance REZPEG; but that renders them untenable because the Agreement defines the scope of Lilly's obligations with respect to REZPEG—i.e., to make efforts in line with a comparable Lilly product. A party like Nektar cannot use an implied covenant to achieve a different, more lenient standard; that would be an improper attempt to "impose an obligation that is inconsistent with express contractual terms." *InspiRx*, 554 F. Supp. 3d at 566. Nektar and Lilly agreed to specific language that required only reasonable "efforts, expertise and resources" similar to those Lilly used for comparable products on an indication-by-indication basis, and that further gave Lilly final say over developmental disputes. Nektar cannot now rewrite that bargain by imposing inconsistent or additional duties, let alone asserting a right to second-guess Lilly's choices via lawsuit.

Third, any claim that Lilly's termination of the Agreement violated the covenant is especially defective. The Agreement allowed "Termination ***At Will*** by Lilly," §11.2 (emphasis added), and "the covenant of good faith and fair dealing cannot negate [an] express contractual right to terminate." *767 Third Ave. v. Greble & Finger*, 778 N.Y.S.2d 157, 158 (N.Y. App. Div. 2004). Nektar's dissatisfaction with the termination provision—which ***Nektar asked Lilly to invoke—***is no basis to rewrite it.

C. Nektar Cannot Prove A Post-Termination Breach.

Nektar has claimed that Lilly violated its post-termination cooperation obligations by not transferring REZPEG-related materials within 90 days. But Nektar misreads the text of the Agreement, and in any event the undisputed evidence does not support its assertions.

As to the Agreement, there was no 90-day deadline to transfer REZPEG-related materials. Nektar references §11.***2***, which refers to a "ninety (90) day period" post-termination during which "the parties shall cooperate in the ***wind down*** of applicable activities under this Agreement." (Emphasis added.) But that language does not require completion of the post-termination ***transfer*** in that window. Instead, §11.4(b)(ii) separately sets out the transfer requirement, which just requires Lilly to "reasonably cooperate with Nektar to facilitate a smooth, orderly and prompt transition (including during any notice period hereunder) of any ongoing Product development activities." Given that this clause specifically contemplates that the transition period might "include[]"—but is ***not*** limited to—the 90-day "notice period," Nektar's suggestion that there was a strict 90-day clock is wrong.

Nektar also admits Lilly has been more than "[redacted]," *id.*, and indeed now admits there is ***nothing*** left outstanding. Earlier in this case, Nektar complained about Lilly's [redacted], *see* Ex. 44, Resp. No. 17, at 13-14, which Nektar recognized [redacted]. Ex. 67, Nektar00000597215; Ex. 68, LLY02197528, at 529. The parties thus worked together on the transfer, during which Nektar acknowledged that the process was [redacted] Ex. 45, and that it had [redacted], *see* Ex. 4, 170:17-171:7, 183:4-13. Ultimately, Nektar could not identify ***any*** documents that it had not received from [redacted]. *Id.* 177:9-18. Nektar had [redacted]. *Id.* 182:9-17. And Nektar eventually conceded that there were "[redacted]" *Id.* 179:21-25. "[redacted]" *Id.*

CONCLUSION

It is time for this case to come to an end. The undisputed evidence shows that Lilly fully complied with its obligations under the Agreement, Nektar has suffered no harm, and the plain terms of the Agreement preclude any recovery. Lilly is entitled to summary judgment as a matter of law.

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Respectfully submitted,

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